



## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:

Filing Date:

For:

Ringeisen, T.

10/010,304 Serial No.:

November 8, 2001

Group Art Unit: 1615

Examiner: Young, Micah-Paul Atty. Docket No.: KN P-0020

Method for Making a Porous Polymeric Material

**Assistant Commissioner for Patents** Washington, D.C. 20231

## **AMENDMENT**

Dear Sir:

In regard to the Office Action dated July 03, 2002, please amend the above-identified patent application as follows:

## IN THE SPECIFICATION

Please substitute the following paragraphs for the paragraphs of record in the present application. Applicant attaches as an Appendix a set of Specification Amendments showing the specific text deletions as [bracketing], and text additions as underscoring.

The second paragraph on page 2:

Compliance problems with woven polyethylene terephthalate and drawn out polytetrafluoroethylene prompted interest in thermoplastic elastomers for use as blood conduits. Medical grade polyurethane (PU) copolymers are an important member of the thermoplastic elastomer family. PU's are generally composed of short, alternating polydisperse blocks of soft and hard segment units. The soft segment is typically a polyester, polyether or a polyalkyldiol (e.g., polytetramethylene oxide). The hard segment is formed by polymerization of either an aliphatic or aromatic diisocyanate with chain extender (diamine or glycol). The resulting product containing the urethane or urea linkage is copolymerized with the soft segment to produce a variety of polyurethane formulations. PU's have been tested as blood conduits for over 30 years. Medical grade PU's, in general, have material properties that make it an excellent biomaterial for the manufacture of vascular grafts as compared to other commercial plastics. These properties include excellent tensile strength, flexibility, toughness, resistance to degradation and fatigue, as well as biocompatiblity. Unfortunately, despite these positive qualities, it became clear in the early 1980s that conventional ether-based polyurethane elastomers presented long-term biostabilty issues as well as some concern over potential carcinogenic degradation products. Further, in contrast to excellent performance in animal trials, clinically disappointing results with PU-based grafts diminished the attractiveness of the material for this application.